

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Geoffrey S. Martin et al.	)	
		)	
For:	MULTIPLE LUMEN CATHETER	)	
		)	
Continuation Application of:		)	
		)	
Serial No.:	139,705	)	Group Art Unit
		)	3262
Filing Date:	August 25, 1998	)	
		)	
Prior Examiner:	Ronald K. Stright, Jr.	)	

TRANSMITTAL FOR PRELIMINARY AMENDMENT

Box: PATENT APPLICATION  
Commissioner for Patents  
United States Patent and Trademark Office  
Washington, D. C. 20231

Sir:

Transmitted herewith is a Preliminary Amendment for entry in the above-identified application.

- ☐ Small entity status of this application under 37 C.F.R. § 1.9 and § 1.27 has been established by a verified statement previously submitted.
- ☒ To secure the approval of the Examiner for proposed amendments to the drawings, enclosed are the following:
- ☒ Letter to the Official Draftsperson;
- ☒ Set of nine (9) sheets of informal drawings containing Figures 1-19 including the proposed amendments therein; and
- ☒ A duplicate set of the nine (9) sheets of informal drawings with the changes therein highlighted in red.

\_\_\_ To render the transmitted Preliminary Amendment timely filed enclosed are the following:

\_\_\_ Petition for a \_\_\_\_\_-Month Extension of Time for a period of \_\_\_\_\_ (\_\_\_) months; and

\_\_\_ Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ comprising the corresponding fee required in relation thereto.

\_\_\_ No additional fee is required.

x Duplicate copies of this sheet are attached.

The fee has been calculated as follows for other than a small entity applicant:

CLAIM INVENTORY			SMALL ENTITY		OR	OTHER THAN A SMALL ENTITY	
Claims Remaining After	Highest No. Previously Paid For	Present Extra	Rate	Additional Fee		Rate	Additional Fee
Total 24	Minus 20	4	\$ 9.00	--		\$18.00	\$ 72.00
Indep. 4	Minus 3	1	\$40.00	--		\$80.00	\$ 80.00
First Multiple Dependent Claim			\$135.00	--		\$270.00	\$ 0.00
Additional Fee			TOTAL			TOTAL	\$ 152.00

\_\_\_ Please charge my Deposit Account No. 20-1469 in the amount of \_\_\_\_\_.

x Check No. 16098 in the amount of \$152.00 for additional claims, if any, is enclosed.


x The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 20-1469. Duplicate copies of this sheet are attached.

x Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims.

x Any patent application processing fees under 37 C.F.R. § 1.17.

DATED this 27<sup>th</sup> day of March, 2001.

Respectfully submitted,



KENT S. BURNINGHAM  
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KSB/jml

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Docket: 2409.3273.3US

EXPRESS MAIL LABEL NO. EL740534444US

PATENT APPLICATION  
Docket No. 2409.3273.3US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Geoffrey S. Martin et al.	)	
		)	
For:	MULTIPLE LUMEN CATHETER	)	
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Continuation Application of:		)	
		)	
Serial No.:	139,705	)	Group Art Unit
		)	3262
Filing Date:	August 25, 1998	)	
		)	
Prior Examiner:	Ronald K. Stright, Jr.	)	

APPENDIX A TO PRELIMINARY AMENDMENT:  
Detail of Amendments to Specification as Originally Filed

Box: PATENT APPLICATION  
Commissioner for Patents  
United States Patent and Trademark Office  
Washington, D. C. 20231

Sir:

Prior to an examination on the merits, kindly amend the specification of the above-captioned continuation application as originally filed as indicated below:

Page 2, line 3, immediately before Paragraph No. [0001], insert and center the following heading:

--RELATED APPLICATIONS--

[0001] This application is a continuation application of copending United States Patent Application Serial No. [08/205,331] 139,705 that was filed on [03/03/94 which is a continuation of Application Serial No. 07/785,351 filed on 10/30/91 which is a continuation of Application Serial No. 07/288,364 filed on 12/22/88 and now U.S. Serial No. 5,195,962.] August 25, 1998 (hereinafter “the Parent Application”), and that issued as United States Patent No. 6,206,849 on March 27, 2001. The Parent Application is a continuation application of United States Patent Application Serial No. 481,169 that was filed on June 7, 1995 (hereinafter “the Grandparent Application”), and that issued as United States Patent No. 5,797,869 on August 25, 1998. The Grandparent Application is a continuation application of United States Patent Application Serial No. 205,331 that was filed on March 3, 1994 (hereinafter “the Great-Grandparent Application”), and that issued as United States Patent No. 5,472,417 on December 5, 1995. The Great-Grandparent Application is a continuation application of United States Patent Application Serial No. 785,351 that was filed on October 30, 1991 (hereinafter “the Great-Great-Grandparent Application”), and that is now abandoned. The Great-Great-Grandparent Application is a continuation application of United States Patent Application Serial No. 288,364 that was filed on December 27, 1988 (hereinafter “the Great-Great-Great-Grandparent Application”), and that issued as United States Patent Application No. 5,195,962 on March 23, 1993. This application is also related to United States Patent Application Serial No. 699,421 that was filed on May 31, 1991, as a divisional application of the Great-Great-Great-Grandparent Application, and that issued as United States Patent No. 5,135,599 on August 4, 1992.

Page 2, line 9, immediately before Paragraph No. [0002], delete the original heading and substitute centered therefor the following:

--BACKGROUND--

Page 2, lines 10-12, enhance Paragraph No. [0002] and subdivide as follows into two (2) paragraphs:

**[0002]** 1. Field of the Invention.

**[0002.1]** This invention relates to a multiple lumen catheter and more particularly to such a catheter for insertion into a vein of a patient to be used in haemodialysis treatments. The invention also relates to methods for manufacturing the multiple lumen catheter.

Page 2, line 14, immediately before Paragraph No. [0003], delete the original heading.

Page 2, lines 15-22, enhance Paragraph No. [0003] and subdivide as follows into two (2) paragraphs:

**[0003]** 2. Background Art.

**[0003.1]** Multiple lumen catheters have been available for many years for a variety of medical purposes. It is only in recent years, however, that such catheters have been developed for use in haemodialysis. The general form of multiple lumen catheters goes back to as early as 1882 when Pfarre patented such a catheter in the United States under Serial No. 256,590. This patent teaches a flexible dual lumen catheter which is used primarily for cleaning and drainage of, for

example, the bladder, rectum, stomach and ear. In this type of catheterization, the catheter is introduced into an existing body orifice without the use of any puncturing needle or guidewire.

Page 7, line 10, immediately before Paragraph No. [0017], delete the underlining in the original heading to produce the following:

--BRIEF DESCRIPTION OF THE DRAWINGS--

[0029] Fig. 16 is a perspective view of a plug for use in making yet another embodiment of the catheter; [and]

[0030] Fig. 17 is a sectional view of still another embodiment of the catheter and using a separate bonded tip;[.]

Page 9, line 1, immediately before Paragraph No. [0033] delete the underlining in the original heading and insert --DETAILED-- at the beginning of the heading to produce the following:

--DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS--

[0037] The IV tube 35 is terminated at its outer end in a luer lock fitting 39 for receiving a syringe or male luer lock connector.

[0040] As will be described in more detail with reference to subsequent views, the tube 35 is aligned with a central lumen to permit the Seldinger wire 21 to pass through the catheter. The

wires [exists at] exit distal end 28 of catheter body 26 through a tip aperture 64 at the apex of tip 29 which is essentially conical so that the catheter can slide over the wire and into the patient during insertion. The extraction and return tubes 32, 34 are linked at connector 30 with lumens in the body 26 to connect with respective groups of side apertures 44, 45 (some of which can be seen in this view) near the distal end of the catheter 28. As a result, when inserted and in use, blood can be removed and returned in a closed loop with a haemodialysis machine using the tubes 32, 34. Between treatments the tube 35 is available for intravenous infusion of liquid medicaments.

[0042] The extraction lumen 50 is blocked short of the tip 29 by a first insert 56 which is formed of polyurethane and bonded in place using a suitable solvent such as cyclohexanane, leaving a hollow extension A of extraction lumen 50 distal of first insert 56. Extraction apertures 44 are provided in the outer wall 46 of the cylindrical portion 26, just short of the insert 56, to permit blood to flow from the patient's vein into the extraction lumen 50 and thus through the connector 30 to the extraction tube 32 and the dialysis machine. It should be noted that the apertures 44 are conveniently circular but may be of any suitable shape or size including scaphoid. Also, further extraction apertures may be provided around the lumen 50 as required consistent with the aperture nearest the tip being immediately adjacent the insert 56 to minimize dead spaces.

[0043] The return lumen 52 is similarly blocked by a second insert 60 immediately adjacent the last of several return apertures 45. This last aperture is positioned closer to the tip 29 than is the last of the intake apertures 44 in the extraction lumen 50 to minimize the risk of cross flow as returning blood finds its way back into the lumen 50. A hollow extension B of return lumen 52



remains distal of second insert 60. Although some cross-flow is not critical, excess cross-flow will extend the time needed for haemodialysis.

[0046] Before shaping the tapered tip 29, the inserts 56, 60 are positioned and affixed in the respective lumens 50, 52 as shown in Fig. 3. The inserts are shaped to the cross-section of the lumens and affixed as previously described. A cylindrical wire 66 (shown in [chain dotted] chain-dotted outline), of corresponding diameter to that of the guide wire 21 (Fig. 2), is inserted through the IV lumen 54 to extend from the distal end of the tubing which is then located in a conical tapered mould 68 (shown in chain-dotted outline). The extrusion is heated by R.F. and as it softens it is pushed into the mould 68 in the direction of arrow D, such that the outer wall 46 and the septum 48 merge at the tip 29. The end of the body assumes a conical tapered shape with a radiused end and the material masses in the lumens 50, 52 forming ends 70, 72. The IV lumen 54 retains its internal shape because it is supported on the wire 66. The now tapered tip is cooled to some extent and then removed from the mould 68 and allowed to cool further and harden.

[0055] It will be seen in Fig. 10, that after the mandrels are engaged, the second sleeve 74 and contained portion of the extrusion are expanded to form connector 30 and, after completion, the appearance of connector 30 will be as shown in Fig. 11.

[0064] The tip structure shown in Fig. 3 can be made in a number of ways. An alternative is shown in Figs. 13 and 14. For ease of reference the reference numerals used in relation to these figures correspond to those used above prefixed with the numeral 1. The distal end 128 and tip 129

of a catheter has inserts 156, 160 which extend to fill the unused portions of the extraction and return lumens. The inserts are entered in the lumens 150, 152 and may be affixed therein by a solvent. When the end 128 is heated in the mould 168 the inserts 156, 160 are softened and deformed and the outer wall 146 collapses to merge with the septum 148. The leading ends of the inserts 156, 160 also merge with the septum 148, as represented by the ghost outlines in Figs. 13 and 14. The resulting catheter has an appearance similar to the catheter described above with a tip opening 164, but with a stiffer leading end.

[0067] Reference is now made to Fig. 16 to describe a moulded plug of polyurethane for use in making tips. This plug P has end pieces 200,202 shaped to fit snugly in the lumens 50, 52 (Fig. 3). The end pieces are attached to respective spacers 204,206 which depend from a hub 208 at respective weakened joints 210,212. The hub has a central opening 214 matching the third lumen 54 so that the wire used in moulding can be used to locate the hub centrally.

Page 19, line 19, through page 20, line 10, amend Paragraph No. [0068] and subdivide as follows into two (2) paragraphs:

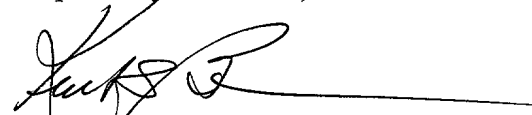
[0068] The procedure, when using the plug P of Fig. 16, is to first bend the spacers 204,206 about the joints 210,212 so that the end pieces 200,202 come together for insertion in the end of the extruded body 26. The pieces are pushed home with solvent until the hub 208 meets the end of the body. The pieces 200,202 will then automatically be in the required positions controlled by the lengths of the spacers 204,206. Moulding then proceeds as before so that the hub and adjacent parts of the spacers will become integral portions of the tip.

[0068.1] A further embodiment is shown in Fig. 17. This structure includes a separate moulded tip 216 preferably of polyurethane, which is engaged in and bonded to the [end of the extrusion] distal end F of an extruded catheter body E. The tip 216 has an outer conical form and defines a central opening 218 [forming] at one end of a central passageway G that forms a continuation of the third lumen 220. A pair of extensions 222, 224 are shaped to fit in the respective lumens 226, 228 and have lengths to match the positions of the apertures 230, 232 in the side wall of the lumens. The ends of the extensions are preferably shaped to meet the apertures and complement the natural flow patterns so that dead spaces will be minimized, if not eliminated.

[0069] The structure shown in Fig. 17 can also be partly formed by heating in a mould to blend the joint between the tip and the extrusion. This technique can also be used to [part form] form part of the assembly to improve the tip, if necessary.

DATED this 27<sup>th</sup> day of March, 2001.

Respectfully submitted,



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KSB/jml  
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Docket: 2409.3273.3US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Geoffrey S. Martin et al. )  
For: MULTIPLE LUMEN CATHETER )  
Continuation Application of: )  
Serial No.: 139,705 ) Group Art Unit  
Filing Date: August 25, 1998 ) 3262  
Prior Examiner: Ronald K. Stright, Jr. )

TRANSMITTAL FOR PRELIMINARY AMENDMENT

Box: PATENT APPLICATION  
Commissioner for Patents  
United States Patent and Trademark Office  
Washington, D. C. 20231

Sir:

Transmitted herewith is a Preliminary Amendment for entry in the above-identified application.

- Small entity status of this application under 37 C.F.R. § 1.9 and § 1.27 has been established by a verified statement previously submitted.
- x To secure the approval of the Examiner for proposed amendments to the drawings, enclosed are the following:
- x Letter to the Official Draftsperson;
- x Set of nine (9) sheets of informal drawings containing Figures 1-19 including the proposed amendments therein; and
- x A duplicate set of the nine (9) sheets of informal drawings with the changes therein highlighted in red.

\_\_\_ To render the transmitted Preliminary Amendment timely filed enclosed are the following:

\_\_\_ Petition for a \_\_\_\_\_-Month Extension of Time for a period of \_\_\_\_\_ ( ) months; and

\_\_\_ Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ comprising the corresponding fee required in relation thereto.

\_\_\_ No additional fee is required.

x Duplicate copies of this sheet are attached.

The fee has been calculated as follows for other than a small entity applicant:

CLAIM INVENTORY			SMALL ENTITY		OR	OTHER THAN A SMALL ENTITY	
Claims Remaining After	Highest No. Previously Paid For	Present Extra	Rate	Additional Fee		Rate	Additional Fee
Total 24	Minus 20	4	\$ 9.00	--		\$18.00	\$ 72.00
Indep. 4	Minus 3	1	\$40.00	--		\$80.00	\$ 80.00
First Multiple Dependent Claim			\$135.00	--		\$270.00	\$ 0.00
Additional Fee			TOTAL			TOTAL	\$ 152.00

\_\_\_ Please charge my Deposit Account No. 20-1469 in the amount of \_\_\_\_\_.

x Check No. 16098 in the amount of \$152.00 for additional claims, if any, is enclosed.


x The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 20-1469. Duplicate copies of this sheet are attached.

x Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims.

x Any patent application processing fees under 37 C.F.R. § 1.17.

DATED this 27<sup>th</sup> day of March, 2001.

Respectfully submitted,



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Docket: 2409.3273.3US

EXPRESS MAIL LABEL NO. EL740534444US

PATENT APPLICATION  
Docket No. 2409.3273.3US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Geoffrey S. Martin et al.	)	
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For:	MULTIPLE LUMEN CATHETER	)	
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Continuation Application of:		)	
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Serial No.:	139,705	)	Group Art Unit
		)	3262
Filing Date:	August 25, 1998	)	
		)	
Prior Examiner:	Ronald K. Stright, Jr.	)	

PRELIMINARY AMENDMENT

Box: PATENT APPLICATION  
Commissioner for Patents  
United States Patent and Trademark Office  
Washington, D. C. 20231

Sir:

Prior to an examination on the merits, kindly amend the above-referenced continuation application as follows:

IN THE SPECIFICATION:

Replace the following paragraphs as originally filed with the indicated paragraphs, which are presented hereinafter:

<u>Originally Filed Paragraph No.</u>	<u>New Paragraph No(s).</u>
[0001]	[0001]
[0002]	[0002] and [0002.1]
[0003]	[0003] and [0003.1]
[0029]	[0029]
[0030]	[0030]
[0037]	[0037]
[0040]	[0040]
[0042]	[0042]
[0043]	[0043]
[0046]	[0046]
[0055]	[0055]
[0064]	[0064]
[0067]	[0067]
[0068]	[0068] and [0068.1]
[0069]	[0069]

Amend the headings used throughout the specification as indicated below using descriptions and reference to page and line of the specification as originally filed.

Transmitted as Appendix A to this Preliminary Amendment are the headings as originally filed and the above-listed paragraphs as originally filed in which the amendments to be effected thereto are detailed by description or by standard bracket-and-underline notation.



Page 2, line 3, immediately before Paragraph No. [0001] insert and center the heading:

## RELATED APPLICATIONS

[0001] This application is a continuation application of copending United States Patent Application Serial No. 139,705 that was filed on August 25, 1998 (hereinafter “the Parent Application”), and that issued as United States Patent No. 6,206,849 on March 27, 2001. The Parent Application is a continuation application of United States Patent Application Serial No. 481,169 that was filed on June 7, 1995 (hereinafter “the Grandparent Application”), and that issued as United States Patent No. 5,797,869 on August 25, 1998. The Grandparent Application is a continuation application of United States Patent Application Serial No. 205,331 that was filed on March 3, 1994 (hereinafter “the Great-Grandparent Application”), and that issued as United States Patent No. 5,472,417 on December 5, 1995. The Great-Grandparent Application is a continuation application of United States Patent Application Serial No. 785,351 that was filed on October 30, 1991 (hereinafter “the Great-Great-Grandparent Application”), and that is now abandoned. The Great-Great-Grandparent Application is a continuation application of United States Patent Application Serial No. 288,364 that was filed on December 27, 1988 (hereinafter “the Great-Great-Great-Grandparent Application”), and that issued as United States Patent Application No. 5,195,962 on March 23, 1993. This application is also related to United States Patent Application Serial No. 699,421 that was filed on May 31, 1991, as a divisional application of the Great-Great-Great-Grandparent Application, and that issued as United States Patent No. 5,135,599 on August 4, 1992.

Page 2, line 9, immediately before Paragraph No. [0002], delete the original heading and substitute centered therefor the following heading:

## BACKGROUND

**[0002]** Field of the Invention.

**[0002.1]** This invention relates to a multiple lumen catheter and more particularly to such a catheter for insertion into a vein of a patient to be used in haemodialysis treatments. The invention also relates to methods for manufacturing the multiple lumen catheter.

**[0003]** Background Art.

**[0003.1]** Multiple lumen catheters have been available for many years for a variety of medical purposes. It is only in recent years, however, that such catheters have been developed for use in haemodialysis. The general form of multiple lumen catheters goes back to as early as 1882 when Pfarre patented such a catheter in the United States under Serial No. 256,590. This patent teaches a flexible dual lumen catheter which is used primarily for cleaning and drainage of, for example, the bladder, rectum, stomach and ear. In this type of catheterization, the catheter is introduced into an existing body orifice without the use of any puncturing needle or guidewire.

Page 7, line 10, immediately before Paragraph No. [0017], delete the underlining in the original heading to produce the following:

## BRIEF DESCRIPTION OF THE DRAWINGS

[0029] Fig. 16 is a perspective view of a plug for use in making yet another embodiment of the catheter;

[0030] Fig. 17 is a sectional view of still another embodiment of the catheter and using a separate bonded tip;

Page 9, line 1, immediately before Paragraph No. [0033], delete the underlining in the original heading and insert --DETAILED-- at the beginning of the heading to produce the following:

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0037] The IV tube 35 is terminated at its outer end in a luer lock fitting 39 for receiving a syringe or male luer lock connector.

[0040] As will be described in more detail with reference to subsequent views, the tube 35 is aligned with a central lumen to permit the Seldinger wire 21 to pass through the catheter. The wires exit distal end 28 of catheter body 26 through a tip aperture 64 at the apex of tip 29 which is essentially conical so that the catheter can slide over the wire and into the patient during insertion. The extraction and return tubes 32, 34 are linked at connector 30 with lumens in the body 26 to connect with respective groups of side apertures 44, 45 (some of which can be seen in this view) near the distal end of the catheter 28. As a result, when inserted and in use, blood can be removed and returned in a closed loop with a haemodialysis machine using the tubes 32, 34. Between treatments the tube 35 is available for intravenous infusion of liquid medicaments.

[0042] The extraction lumen 50 is blocked short of the tip 29 by a first insert 56 which is formed of polyurethane and bonded in place using a suitable solvent such as cyclohexanane, leaving a hollow extension A of extraction lumen 50 distal of first insert 56. Extraction apertures 44 are provided in the outer wall 46 of the cylindrical portion 26, just short of the insert 56, to permit blood to flow from the patient's vein into the extraction lumen 50 and thus through the connector 30 to the extraction tube 32 and the dialysis machine. It should be noted that the apertures 44 are conveniently circular but may be of any suitable shape or size including scaphoid. Also, further extraction apertures may be provided around the lumen 50 as required consistent with the aperture nearest the tip being immediately adjacent the insert 56 to minimize dead spaces.

[0043] The return lumen 52 is similarly blocked by a second insert 60 immediately adjacent the last of several return apertures 45. This last aperture is positioned closer to the tip 29 than is the last of the intake apertures 44 in the extraction lumen 50 to minimize the risk of cross flow as returning blood finds its way back into the lumen 50. A hollow extension B of return lumen 52 remains distal of second insert 60. Although some cross-flow is not critical, excess cross-flow will extend the time needed for haemodialysis.

[0046] Before shaping the tapered tip 29, the inserts 56, 60 are positioned and affixed in the respective lumens 50, 52 as shown in Fig. 3. The inserts are shaped to the cross-section of the lumens and affixed as previously described. A cylindrical wire 66 (shown in chain-dotted outline), of corresponding diameter to that of the guide wire 21 (Fig. 2), is inserted through the IV lumen 54 to extend from the distal end of the tubing which is then located in a conical tapered mould 68

(shown in chain-dotted outline). The extrusion is heated by R.F. and as it softens it is pushed into the mould 68 in the direction of arrow D, such that the outer wall 46 and the septum 48 merge at the tip 29. The end of the body assumes a conical tapered shape with a radiused end and the material masses in the lumens 50, 52 forming ends 70, 72. The IV lumen 54 retains its internal shape because it is supported on the wire 66. The now tapered tip is cooled to some extent and then removed from the mould 68 and allowed to cool further and harden.

[0055] It will be seen in Fig. 10, that after the mandrels are engaged, the second sleeve 74 and contained portion of the extrusion are expanded to form connector 30 and, after completion, the appearance of connector 30 will be as shown in Fig. 11.

[0064] The tip structure shown in Fig. 3 can be made in a number of ways. An alternative is shown in Figs. 13 and 14. For ease of reference the reference numerals used in relation to these figures correspond to those used above prefixed with the numeral 1. The distal end 128 and tip 129 of a catheter has inserts 156, 160 which extend to fill the unused portions of the extraction and return lumens. The inserts are entered in the lumens 150, 152 and may be affixed therein by a solvent. When the end 128 is heated in the mould 168 the inserts 156, 160 are softened and deformed and the outer wall 146 collapses to merge with the septum 148. The leading ends of the inserts 156, 160 also merge with the septum 148, as represented by the ghost outlines in Figs. 13 and 14. The resulting catheter has an appearance similar to the catheter described above with a tip opening 164, but with a stiffer leading end.

[0067] Reference is now made to Fig. 16 to describe a moulded plug of polyurethane for use in making tips. This plug P has end pieces 200,202 shaped to fit snugly in the lumens 50, 52 (Fig. 3). The end pieces are attached to respective spacers 204,206 which depend from a hub 208 at respective weakened joints 210,212. The hub has a central opening 214 matching the third lumen 54 so that the wire used in moulding can be used to locate the hub centrally.

[0068] The procedure, when using the plug P of Fig. 16, is to first bend the spacers 204,206 about the joints 210,212 so that the end pieces 200,202 come together for insertion in the end of the extruded body 26. The pieces are pushed home with solvent until the hub 208 meets the end of the body. The pieces 200,202 will then automatically be in the required positions controlled by the lengths of the spacers 204,206. Moulding then proceeds as before so that the hub and adjacent parts of the spacers will become integral portions of the tip.

[0068.1] A further embodiment is shown in Fig. 17. This structure includes a separate moulded tip 216 preferably of polyurethane, which is engaged in and bonded to the distal end F of an extruded catheter body E. The tip 216 has an outer conical form and defines a central opening 218 at one end of a central passageway G that forms a continuation of the third lumen 220. A pair of extensions 222, 224 are shaped to fit in the respective lumens 226, 228 and have lengths to match the positions of the apertures 230,232 in the side wall of the lumens. The ends of the extensions are preferably shaped to meet the apertures and complement the natural flow patterns so that dead spaces will be minimized, if not eliminated.

[0069] The structure shown in Fig. 17 can also be partly formed by heating in a mould to blend the joint between the tip and the extrusion. This technique can also be used to form part of the assembly to improve the tip, if necessary.

IN THE CLAIMS:

Cancel Claim1.

Add the following new Claims 24-47:

-- 24. A triple lumen vascular access catheter capable by advancement along an insertion guide wire of percutaneous entry into a blood vessel of the cardiovascular system of a patient, said catheter comprising:

- a. an outer tube having a proximal end and a distal end;
- b. an inner tube having a proximal end and a distal end and defining therewithin a first lumen, said inner tube having an outer diameter less than the inner diameter of said outer tube, said inner tube being disposed within said outer tube to define an interior space between the outside of said inner tube and the inside of said outer tube, the inner diameter of said inner tube being so sized as to accommodate an insertion guide wire having an outer diameter in a range from about 0.036 inches to about 0.038 inches;
- c. a first septum extending from a first point on the outside of said inner tube to a first point on the inside of said outer tube;
- d. a second septum extending between a second point on said outside of said inner tube and a second point on said inside of said outer tube, said first septum and said second septum thereby separating said interior space into a second lumen located on one side of said first septum, said inner tube, and said second septum, and a third lumen located on the opposite side of said first septum, said inner tube, and said second septum;



e. a tapered distal tip section at said distal end of said outer tube, the outer surface of said distal tip section tapering radially inwardly from said distal end of said outer tube toward said inner tube and terminating in a first aperture through which said first lumen communicates with the exterior of said distal tip section;

f. a second aperture formed through said outer tube proximate said distal end thereof, said second lumen communicating with the exterior of said outer tube through said second aperture; and

g. a third aperture formed through said outer tube proximate said distal end thereof, said third lumen communicating with the exterior of said outer tube through said third aperture.

25. A catheter as recited in Claim 24, wherein the size of said inner diameter of said inner tube is about 0.04 inches.

26. A catheter as recited in Claim 24, wherein the distance between said first point on said outside of said inner tube and said first point on said inside of said outer tube is equal to the distance between said second point on said outside of said inner tube and said second point on said inside of said outer tube.

27. A catheter as recited in Claim 26, wherein said first septum and said second septum are coplanar.

28. A catheter as recited in Claim 26, wherein the transverse cross section of said second lumen is congruent with the transverse cross section of said third lumen.

29. A catheter as recited in Claim 28, wherein each of said second lumen and said third lumen have a C-shaped transverse cross section.

30. A catheter as recited in Claim 28, wherein each of said second lumen and said third lumen have a D-shaped transverse cross section.

31. A catheter as recited in Claim 24, wherein said outer surface of said outer wall of said distal tip section tapers continuously from said distal end of said outer tube to said first aperture.

32. A triple lumen catheter comprising:

a. a catheter body comprising:

i. an outer tube having a proximal end and a distal end;

ii. an inner tube having a proximal end and a distal end and defining therewithin a first lumen, said inner tube having an outer diameter less than the inner diameter of said outer tube, said inner tube being disposed within said outer tube to define an interior space between the outside of said inner tube and the inside of said outer tube;

iii. a first septum extending from a first point on the outside of said inner tube to a first point on the inside of said outer tube;

iv. a second septum extending between a second point on said outside of said inner tube and a second point on said inside of said outer tube, said first septum and said second septum thereby separating said interior space into a second lumen located on one side of said first septum, said inner tube, and said second septum, and a third lumen located on the opposite side of said first septum, said inner tube, and said second septum; and

b. a tapered distal tip section at said distal end of said outer tube, said distal tip section comprising:

i. a cylindrical central extension having an outer diameter less than the outer diameter of said outer tube and enclosing a third passageway, said central extension having a proximal end secured to said distal end of said inner tube in fluid communication with said first lumen and a distal end terminating in a first aperture through which said first lumen communicates by way of said fluid passageway with the exterior of said distal tip section; and

ii. a shoulder between said distal end of said outer tube and said proximal end of said central extension smoothly and continuously interconnecting the outer surface of said second tube with the outer surface of said central extension.

33. A catheter recited in Claim 32, wherein the inner surface of said cylindrical extension is smoothly and continuously connected to the inner surface of said inner tube at said distal end thereof.

34. A catheter as recited in Claim 32, wherein the area of the transverse cross section of said first lumen is equal to the area of the transverse cross section of said fluid passageway in said central extension.

35. A catheter as recited in Claim 32, wherein said shoulder of said distal tip section tapers radially inwardly in a circularly symmetric manner from said distal end of said outer tube into engagement with said cylindrical central extension.

36. A catheter as recited in Claim 35, further comprising:

a. a second aperture formed through said outer tube proximate said distal end thereof, said second lumen communicating with the exterior of said outer tube through said second aperture; and

b. a third aperture formed through said outer tube proximate said distal end thereof, said third lumen communicating with the exterior of said outer tube through said third aperture.

37. A catheter as recited in Claim 36, wherein said second aperture is located further from said first aperture than said third aperture.

38. A catheter as recited in Claim 36, wherein a solid insert fills each of said second lumen and said third lumen distal of said second aperture and said third aperture, respectively.

39. A catheter as recited in Claim 36, wherein a plug terminates each of said second lumen and said third lumen distal of said second aperture and said third aperture, respectively.

40. A catheter as recited in Claim 32, wherein the material of said cylindrical central extension exhibits physical characteristics different from the physical characteristics of the material of said outer tube.

41. A catheter as recited in Claim 40, wherein said material of said cylindrical central extension is softer than said material of said outer tube.

42. A triple lumen catheter comprising:

a. a catheter body comprising:

i. an outer tube having a proximal end and a distal end;

ii. an inner tube having a proximal end and a distal end and defining therewithin a first lumen, said inner tube having an outer diameter less than the inner diameter of said outer tube, said inner tube being disposed within said outer tube to define an interior space between the outside of said inner tube and the inside of said outer tube;

iii. a first septum extending from a first point on the outside of said inner tube to a first point on the inside of said outer tube; and

iv. a second septum extending between a second point on said outside of said inner tube and a second point on said inside of said outer tube, said first septum

and said second septum thereby separating said interior space into a second lumen located on one side of said first septum, said inner tube, and said second septum, and a third lumen located on the opposite side of said first septum, said inner tube, and said second septum;

b. a circularly symmetric frustoconical distal tip section at said distal end of said outer tube, the outer surface of said distal tip section tapering radially inwardly from said distal end of said outer tube toward said inner tube and terminating in a first aperture at the apex of said distal tip section, said first lumen communicating with the exterior of said distal tip section through said first aperture;

c. a plurality of second apertures formed through said outer tube proximate said distal end thereof, said second lumen communicating with the exterior of said outer tube through said plurality of second apertures;

d. a plurality of third apertures formed through said outer tube further from said distal end thereof than said plurality of said second apertures, said third lumen communicating with the exterior of said outer tube through said plurality of third apertures; and

e. access means attached to said proximal end of said outer tube and said proximal end of said inner tube for affording fluid communication individually with said first lumen, said second lumen, and said third lumen.

43. A catheter as recited in Claim 42, wherein said access means comprises:

- a. a connector attached to said proximal end of said outer tube and said proximal end of said inner tube;
- b. a first access tube attached to said connector and communicating therethrough with said first lumen;
- c. a second access tube attached to said connector and communicating therethrough with said second lumen; and
- d. a third access tube attached to said connector and communicating therethrough with said third lumen.

44. A catheter as recited in Claim 43, further comprising:

- a. cylindrical attachment fitting rotatably mounted on the exterior of said connector; and
- b. a pair of coplanar suture wings extending laterally from opposite sides of said attachment fitting.

45. A catheter as recited in Claim 43, wherein said first access tube carries a closure clamp.

46. A method of manufacturing a triple lumen catheter, said method comprising the steps of:

- a. extruding a catheter body having a circular transverse outer cross section, said catheter body enclosing a longitudinally extending first lumen and a longitudinally extending second lumen separated by a generally planar septum having a bulbous middle portion projecting from one side of said septum into a said first lumen and from the other side of said septum into said second lumen;
- b. forming a third longitudinally extending lumen within said bulbous portion of said septum;
- c. tapering the outer wall of said catheter body inwardly at the distal end thereof into engagement with said bulbous portion of said septum;
- d. terminating each of said first lumen and said second lumen proximal of said distal end of said catheter body; and
- e. forming a first side opening through the outer wall of said catheter body to said first lumen;
- f. forming a second side opening through the outer wall of said catheter body to said second lumen.

47. A method as recited in Claim 46, further comprising the step of extending said bulbous portion of said septum with said third lumen therein distally beyond said outer wall of said catheter body. --



IN THE ABSTRACT:

Replace the abstract as originally filed with that presented below.

Transmitted herewith as Appendix B to this Preliminary Amendment is the abstract as originally filed detailing by description or by standard bracket-and-underline notation the specifics of the amendments effected thereto.

ABSTRACT

A cylindrical elongate body having proximal and distal ends and enclosing two similar longitudinally extending lumens separated by a septum and a further lumen within the septum. A convergently tapered tip extending from the distal end of the body defines part of the further lumen that extends distally beyond the longitudinally extending lumens, while a connector at the proximal end of the body couples plural access tubes in fluid communication with respective individual of the lumens. Openings providing access to each of the longitudinally extending lumens are spaced from one another longitudinally along the body. The further lumen terminates at an opening at the distal end of the tip. The longitudinally extending lumens are blocked immediately distally of the openings.

IN THE DRAWINGS:

Figure 2, add --64-- and an associated lead line to identify the tip aperture at distal end 28 of catheter body 26.

Figure 3, add --54-- and an associated lead line (two locations) to identify the intravenous lumen contained in septum 48;  
add --66-- and an associated lead line to identify the cylindrical wire that is disposed in intravenous lumen 54 during R.F. heating;  
add --A-- and an associated lead line to identify the hollow extension of extraction lumen 50 formed distal of first insert 56;  
add --B-- and an associated lead line to identify the hollow extension of return lumen 52 formed distal of second insert 60; and  
add --D-- in association with the heavy arrow pointing to the right and located on the left side of Figure 3 in order to identify the direction in which catheter body 26 is pushed into mould 68.

Figure 4, add --28-- and an associated lead line with an arrow to identify the distal end of catheter body 26 illustrated in the cross-sectional view provided;  
add --48-- and an associated lead line to identify the portion of the septum on the right side of intravenous lumen 54;  
add --56-- and an associated lead line to identify the first insert; and  
delete “50” and the associated lead line.

Figure 5, add --28-- and an associated lead line with an arrow to identify the distal end of catheter body 26 illustrated in the cross-sectional view provided; add --48-- and an associated lead line to identify the portion of the septum on the left of intravenous lumen 54; add --53-- and an associated lead line to identify the bulbous middle portion of septum 48; add --A-- and an associated lead line to identify the hollow extension of extraction lumen 54 located distal of first insert 56 shown in Figure 3; and add --B-- and an associated lead line to identify the hollow extension of return lumen 52 located distal of second insert 60 shown in Figure 3.

Figure 6, add --28-- and an associated lead line with an arrow to identify the distal end of catheter body 26 illustrated in the end view provided; add --29-- and an associated lead line to identify the conical tapered tip at distal end 28 of catheter body 26; and add --64-- and an associated lead line to identify the tip opening at distal end 28 of catheter body 26;

Figure 8, add --24-- and an associated lead line (two locations) to identify the wing tabs on either side of the figure.

Figure 10, add --30-- and an associated lead line with an arrow to identify the connector at the proximal end of catheter body 26.

Figure 11, add --30-- and an associated lead line with an arrow to identify the connector at the proximal end of catheter body 26.

Figure 13, add --126-- and an associated lead line with an arrow to identify the catheter body illustrated;

add --150-- and an associated lead line to identify the extraction lumen;

add --152-- and an associated lead line to identify the return lumen;

add --153-- and a pair of associated lead lines to identify each side of the bulbous middle portion of septum 48 illustrated in Figure 14;

add --154-- and an associated lead line to identify the intravenous lumen contained in bulbous middle portion 153 of septum 48;

add --156-- and an associated lead line to identify the first insert positioned in extraction lumen 150; and

add --164-- and an associated lead line with an arrow to identify the tip opening at distal end 128 of catheter body 126.

Figure 14, add --128-- and an associated lead line with an arrow to identify the distal end of catheter body 126 illustrated in the cross-sectional view presented;

add --148-- and an associated lead line to identify the septum;

add --153-- and an associated lead line to identify the bulbous middle portion of septum 148;

add --154-- an associated lead line to identify the intravenous lumen contained in bulbous middle portion 153 of septum 148;

add 156-- and an associated lead line to identify the first insert disposed in extraction lumen 150 shown in Figure 13; and

add --160-- and an associated lead line to identify the second insert disposed in return lumen 152 illustrated in Figure 13.

Figure 15, add --128-- and an associated lead line with an arrow to identify the distal end of the catheter body illustrated in the cross-sectional view presented;

add --226-- and an associated lead line with an arrow to identify the catheter body illustrated; and

add --254-- and an associated lead line to identify the intravenous lumen contained in septum 248.

Figure 16, add --P-- and an associated lead line with an arrow to identify the plug illustrated.

Figure 17, change “223” to --228--;  
add --E-- and an associated lead line with an arrow to identify the catheter body illustrated;  
add --F-- and an associated lead line with an arrow to identify the catheter body E; and  
add --G-- and an associated lead line with a double-ended arrow to identify the central passageway in tip 216.

## REMARKS

### A. Amendment to the Specification

The above-listed amendments to the specification include all amendments effected thereto during the prosecution of United States Patent Application Serial No. 139,705 filed August 25, 1998 (hereinafter "the Parent Application"), as well as amendments to the headings used throughout the specification.

The amendments to the headings bring those into conformity with the form and format recommended by the United States Patent and Trademark Office. The balance of the amendments serve the purpose exclusively of permitting the specification to refer with particularity to the figures in view of the several amendments that are also herein proposed to be effected in those figures.

The proposed amendments to the specification do not add new matter, and accordingly entry thereof is respectfully requested.

### B. Amendments to the Claims

New Claims 24-47 are supported by the specification as originally filed.

Accordingly, entry thereof is respectfully requested.

### C. Amendments to the Abstract

The above-listed amendments to the Abstract bring the heading thereof into conformity with the form and format recommended by the United States Patent and Trademark Office and reduce to 150 or less the number of words therein.

Entry thereof is respectfully requested.

D. Amendments to the Figures

The above-listed amendments to the figures include all amendments effected thereto during the prosecution of the Parent Application and serve to bring the figures as originally filed into conformity with the rules of patent practice in effect before the United States Patent and Trademark Office.

The amendments to the figures serve only to identify with reference characters structural features clearly shown in the drawings as originally filed. Therefore, it is respectfully submitted that the above-listed amendments to the drawings do not add new matter, and the approval of the Examiner for the entry thereof is respectfully requested.

For the convenience of the Examiner in this regard, transmitted herewith under cover of a Letter to the Official Draftsperson is a complete set of the figures as originally filed prepared in complete compliance with the formal requirements of the United States Patent and Trademark Office and containing all of the above-listed proposed amendments to those figures. In addition, transmitted therewith is an identical set of the figures with the proposed amendment thereto relative to the figures as originally filed highlighted in red.

E. Conclusion

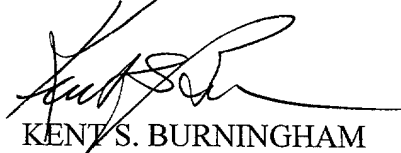
Examination on the merits is respectfully requested of Claims 24-47 newly presented herein.

Should the Examiner encounter any impediment to a prompt allowance of this application, and should that impediment be susceptible to resolution through a telephone conversation, the Examiner is respectfully requested to initiate such a telephone conference with the undersigned.



DATED this 27<sup>th</sup> day of March, 2001.

Respectfully submitted,



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Docket: 2409.3273.3US

EXPRESS MAIL LABEL NO. EL740534444US

PATENT APPLICATION  
Docket No. 2409.3273.3US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Geoffrey S. Martin et al.	)	
		)	
For:	MULTIPLE LUMEN CATHETER	)	
		)	
Continuation Application of:		)	
		)	
Serial No.:	139,705	)	Group Art Unit
		)	3262
Filing Date:	August 25, 1998	)	
		)	
Prior Examiner:	Ronald K. Stright, Jr.	)	

APPENDIX B TO PRELIMINARY AMENDMENT:  
Detail of Amendment to the Abstract as Originally Filed

Box: PATENT APPLICATION  
Commissioner for Patents  
United States Patent and Trademark Office  
Washington, D. C. 20231

Sir:

Kindly amend the abstract of the above-captioned continuation application as originally filed as indicated below:

Page 34, line 1, delete the underlining in the heading and delete "OF THE INVENTION" to produce the following:

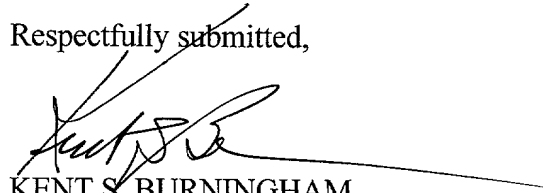
ABSTRACT

Amend the text of the Abstract as follows:

[The invention provides a] A cylindrical elongate body having [extending from a] proximal and [to a] distal ends and enclosing [end, the body defining] two similar longitudinally extending lumens separated by a septum and a further lumen [defined] within the septum.[, a] A convergently tapered tip extending from the distal end of the body defines [defining a] part of the [said] further lumen that extends distally beyond the longitudinally extending lumens, while a connector at the [said] proximal end of the body couples plural access[,] tubes [coupled to the connector and] in fluid communication [through the connector one] with [each of the] respective individual of the lumens.[, the body defining openings] Openings providing access [one] to each of the longitudinally extending lumens are[, said openings being] spaced from one another longitudinally along [of] the body. [and said further lumen extending longitudinally beyond said longitudinally extending lumens and through the tip, the] The further lumen terminates [terminating] at an opening at the distal end of the tip. [and the tip being convergently tapered as it extends longitudinally from said body and the] The longitudinally extending lumens are [being] blocked immediately [adjacent and] distally of the [said] openings.

DATED this 27<sup>th</sup> day of March, 2001.

Respectfully submitted,



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Docket: 2409.3273.3US